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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,219	03/02/2004	Lois Weisman	IOWA:048US 3887	
75	90 10/20/2006			INER
Steven L. Highlander			LIU, SAMUEL W	
Fulbright & Jaw	orski L.L.P.			
Suite 2400		ART UNIT	PAPER NUMBER	
600 Congress Avenue			1656	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<u> </u>								
Office Action Summary		Application No.	Applicant(s)					
		10/791,219	WEISMAN, LOIS					
		Examiner	Art Unit					
		Samuel W. Liu	1653					
Period fo	The MAILING DATE of this communication ap or Reply	pears on the cover sheet with the c	orrespondence address					
WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPL CHEVER IS LONGER, FROM THE MAILING D nsions of time may be available under the provisions of 37 CFR 1.1.2 SIX (6) MONTHS from the mailing date of this communication. In period for reply is specified above, the maximum statutory period are to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION (136(a)). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).					
Status			·					
1)⊠	Responsive to communication(s) filed on <u>05 S</u>	Sentember 2006						
2a)□	This action is FINAL . 2b)⊠ This action is non-final.							
3)□								
<u>ا</u>	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Dispositi	on of Claims	- Aparto Quayro, 1000 C.D. 11, 10	70 0.0.210.					
· · _	•							
	Claim(s) <u>1-60</u> is/are pending in the application.							
	4a) Of the above claim(s) 1-17,20-23 and 27-60 is/are withdrawn from consideration.							
·	Claim(s) is/are allowed.							
6)⊠	· · ·							
7)								
8)[_]	8) Claim(s) are subject to restriction and/or election requirement.							
Applicati	on Papers							
9)🖾	9)⊠ The specification is objected to by the Examiner.							
10)🖂	10)⊠ The drawing(s) filed on <u>02 March 2004</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11)	The oath or declaration is objected to by the E							
Priority ι	ınder 35 U.S.C. § 119							
_	12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:							
۵/۱								
	 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage 							
			in this National Stage					
* 0	application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
	bee the attached detailed Office action for a list	of the certified copies not receive	; a .					
Attachmen	t(s)							
	e of References Cited (PTO-892)	4) Interview Summary						
	e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P						
	r No(s)/Mail Date <u>2/14/05</u> .	6) ⊠ Other: <u>attachment 1</u>						
	<u> </u>							

DETAILED ACTION

Status of the claims

Claims 1-60 are pending.

Examiner note that the claims filed 7/29/04 are identical to the claims filed 3/2/04.

IDS

The references cited in the IDS filed 2/14/05 have been considered by Examiner.

Benefit / priority

Applicant's claim for the benefit of a prior-filed provisional application 60452782 filed 3/7/03 is acknowledged.

Election/Restrictions

Applicants' election (filed 9/5/06) of Group II, claims 16-26 and SEQ ID NO:3 for examination without traverse is acknowledged.

- Claims 1-15 and 27-60 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
- Because claims 16-17, 20-21 and 22-23 are directed to the non-elected SEQ ID NOs: 1, 5 and 7, respectively, these claims are withdrawn from further consideration.

Therefore, claims 18-19 and 24-26 and SEQ ID NO:3 are under examination to the extent that they are drawn to the elected invention.

Specification/claim Objection

The disclosure is objected to because of the following informalities:

(1) On page 2, line 31, "GLUT4" should be spelled out in full for the first instance of use (e.g., "glucose transporter-4"); see also page 4, line 23, "RT-PCR"; line 29, "RIA" and ELISA";

Art Unit: 1656

page 9, line 8, "GLUT1"; page 23, line 25, "SDS/PAGE"; page 24, line 3, "PEG"; and, page 74, line 12, "GFP".

Page 3

- (2) "HPLC" should be spelled <u>first</u> on page <u>23</u>, line 8, instead of first spelling out on page 24, line <u>24</u>.
- (3) On page 6, line 6, "Fig.1 Protein with identity to Vac14p exist in higher eukaryotes" should be changed to "Fig.1 Protein with amino acid sequence identity to Vac14p exist in higher eukaryotes".
- (4) On page 6, lines 9-10, "(left) The NH2-terminal sequence ..." should be changed to "The left panel shows the NH2-terminal sequence ..."; and line 28, "(Right) The COOH-terminal sequence ..." should be changed to "The right panel shows the COOH-terminal sequence ...".
- (5) On page 7, line 11, "FIG.3 The levels of PI3P and PI3,5P2 transiently change in response to hyperosmotic stress" should be changed to "FIG.3 The transient change of levels of PI(3)P and PI(3,5)P₂ in response to hyperosmotic stress". This change is required in view of the consistence between the specification (page 4, line 25 where sets forth "PI(3)P" and "PI(3,5)P₂") and the description to Figure 3. Similar changes should be made throughout the specification.
- (6) On page 12, lines 23 and 31, "PI3,5P2" and line 31, "PI4,5P2" should be changed to "PI(3,5)P2" and "PI(4,5)P2", respectively, for the *consistence* discussed above.
- (7) On page 28, line 4, "SEQ ID NOS:" should be changed to "SEQ ID NOS:". Similar changes should be made throughout the specification.
- (8) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 6, lines 14, 19, 20 and 23; and page 7, line 3.

Art Unit: 1656

Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Applicants may remove "http://" so that the hyperlinker becomes inactive, i.e., the content followed by Http:// can be and should be left behind; and thus, a browser will only interpret the rest of the URL as text.

(9) Abstract of this application should be changed as follows.

We claim an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:3, which involves in the insulin-response pathway.

(10) In claim 25, "said oliogopeptide" should be changed to "said oligopeptide".

Objection to the drawings

- The drawing (Figure 1) filed 3/2/04 is objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the clear depict for indicating "black" and "gray" highlighted in Figure 1 (see the page 6, the description to Figure 1) must be shown. No new matter should be entered.
- The drawing of Figure 2 filed 3/2/04 is objected to under 37 CFR 1.83(a) because this Figure fails to show *color bar* which has been <u>described in the specification</u> (see the brief description to Figure2, page 7, lines 6-10). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be

Art Unit: 1656

Page 5

labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Duplicate Claims -Warning

Applicant is advised that should claims 25 and 26, which are virtually identical in subject matter and scope of the claims, be found allowable, claims 25 and 26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 18-19 and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites "Vac14 Human AA"; the recitation is not apparent as to what "AA" refers. The specification does not define it. Claim 19 which depends from claim 18 is also rejected.

Claim 19 as written does not make it clear whether or not "non-human Vac14 sequences" refers to the amino acid sequences which are not instant SEQ ID NO:3, or/and, not human Vac14 sequence set forth on page 7, line 20, or/and, not human Vac14 sequence discussed on page 89, line 10.

Claim 24 is indefinite as reciting the non-elected subject matters, i.e., SEQ ID NOs:1, 5 and 7 (applicant elected SEQ ID NO:3). Claims 25 and 26 which depend from claim 24 are also rejected.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

In the instant case, the claims are drawn to a method of increasing the efficiency of an intein-mediated protein splicing/ligation comprising expressing a fusion protein comprising said intein.

(1) Physical and/or chemical properties:

Claim 24 and the dependent claims thereto do not describe biological function of the claimed oligopeptide. The instant invention has not been described in such a way that it is clear that the applicant invented what is claimed. Without knowing the assayable biological function(s) of the claimed oligopeptide (claims 24-26), the skilled artisan will not know how to characterize the claimed oligopeptide.

SEQ ID NO:3 consists of 907 amino acid residues whereas the oligopeptide of claims 24-26 has only length ranging from 5 to 30 consecutive residues. This results in numerous peptides having structural alteration 96.7% - 99.4% (corresponding to oligopeptide having 5 to 30 amino acids) compared to the full-length SEQ ID NO:3. The specification fails to teach or provide working examples for biological function of these oligopeptide.

(2) Functional characteristics:

Without knowing the biological function of the claimed oligopeptide, one skilled in the art would be unable to assay or characterize functional peptide in order for the above-mentioned detection and identification, thereby, in order for diagnosing or treating diabetes (see the page 3 of the specification).

(3) Level of skill and knowledge in the art:

When the claimed oligopeptide is produced and isolated (Example 1), the functional parameter is required for one skilled in the art to be able to assay and characterize the produced oligopeptide. Thus, the level of skill in this art is high.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 24-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polypeptide comprising the full-length SEQ ID NO:3, does not reasonably provide enablement for the oligopeptide (claims 24-26) which comprise only 5-30 amino acid residues of instant SEQ ID NO:3. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546(BPAI 1986). They include the nature of the invention, the state of the art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

(1) The scope of the claims/(2) The nature of the invention:

The claims are broadly drawn to a large quantity of variant oligopeptides ranging from 5 to 30 consecutive amino acids of SEQ ID NO:3. The full-length SEQ ID NO:3 consists of 907 amino acid residues; yet, the oligopeptide of claims 24-26 has length ranging from 5 to 30 consecutive residues.

The specification (page 4, the 1st paragraph) sets forth the oligopeptide; however, nowhere in the specification teaches biological function of the oligopeptide. It is of note that, on the same page 4, the specification sets forth antibody binding to the polypeptide comprising fulllength SEQ ID NO:3 but not to the oligopeptide thereof. This application is silent in teaching tat the oligopeptides have activity, e.g., antigenic activity, of the full-length polypeptide. There are numerous fragments (or oligopeptides) derived from the full-length amino acid sequence of SEQ ID NO:3 (907 residues). Hence, the scope of the claims is outside the bounds of the enablement.

(3) The unpredictability of the art:

Application/Control Number: 10/791,219 Page 10

Art Unit: 1656

The specification fails to teach the core sequence(s) critical for the function of the oligopeptide nor how to characterize and use the oligopeptides of SEQ ID NO:3 polypeptide. Thus, one skilled in the art cannot predict which oligopeptide will be functional. Truncation or deletion can result in unpredictable outcome to the protein/enzyme which is mutated; e.g., deletion of amino or carboxyl terminal 40-45 amino acids abolishes activity of α-SNAP (alpha soluble NSF attachment protein) (see page 876, the left column, Barnard et al. (*J. Cell Biol.* (1997) 139, 875-883)). Thus, the function of oligopeptides (fragments) derived from the full-length SEQ ID NO:3 polypeptide is highly unpredictable.

(4) The state of the prior art:

The general knowledge in the rat does not supplement the omitted description because specific, not general, direction is what is needed. The disclosure fails to describe common attribute and characteristics that identify the oligopeptides of SEQ ID NO:3 which have the biological activity. The specification needs to provide the omitted teaching or description in this regard in order for enabling the claimed invention.

(5) The amount of direction/guidance:

The specification does provide neither guidance that teaches how to characterized (based on assayable activity of the oligopeptide, teachings regarding this is silent in the specification) and use the claimed oligopeptide (see above statement) nor information known in the art relative to said use. Therefore, the amount of direction/guidance for enabling the claimed invention lacks. In the absence of the direction/guidance, one skilled in the art is unable to practice the claimed oligopeptide.

(6) The quantity of experimentation necessary:

As discussed above (under factor 3), the specification neither teaches the core sequence(s) critical for the oligopeptide function in order to allow the skilled artisan to be able to identify biological (assayable) activity of the oligopeptide, nor provides the guidance with regard to direction in which the experimentation as to how to use the claimed oligopeptide should proceed. Thus, one skilled in the art cannot extrapolate the disclosed result (function) of the full-length SEQ ID NO:3 polypeptide to the claimed oligopeptides, i.e., fragments of SEQ ID NO:3. Screening for, identifying and using biologically active oligopeptides, therefore, require great quantity of experimentation. Quantity of the oligopeptides (5-30 amino acid residues) derived from SEQ ID NO:3 polypeptide (907 residues) is enormous. Sorting out and characterizing the functional oligopeptides requires undue experimentation.

(7) The relative skill of those in the art:

The level of skill in this art is high and requires at least a molecular biologist with several years of experience in mutagenesis, microbiology as well as knowledge in peptide chemistry.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention. Thus, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillman et al. (US Pat. No. 6087333).

In the patent claim 1, Hillman et al. teach a <u>fragment</u> of a purified polypeptide of SEQ ID NO:1 comprising the sequence: Glu-Gly-Asp-Val-Ala which reads on amino acid residues 292-296 of instant SEQ ID NO:3. On column 4, lines 54-55, Hillman et al. further teach the limitation to said fragment, i.e., the fragment is preferably 5 to 15 amino acids in length; and the oligopeptide "Glu-Gly-Asp-Val-Ala" falls into this limitation. Therefore, the Hillman et al. teaching anticipates instant claim 24-26.

Claims 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lerner et al. (US Pat. No. 5294543).

Art Unit: 1656

On column 4, Lerner et al. teach a bioactive peptide (SEQ ID NO:3) consisting of 19 amino acids, wherein residues 12-18 of Lerner's SEQ ID NO:3 have sequence identity to residues 262-268 of instant SEQ ID NO:3 (see attachment 1, the left panel). The Lerner et al. teachings anticipate instant claims 24-26.

Note that the polynucleotide encoding Lerner's SEQ ID NO:3 is disclosed in the patent claim 21.

Claims 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Homburger et al. (US Pat. No. 6703491 B1).

In "Examples" section, column 92, lines 34-45, and Table 2 (column 348), Homburger et al. teach a peptide (SEQ ID NO:56389) consists of **24** amino acids, wherein residues 7-13 of SEQ ID NO:56389 have sequence identity to residues 745-751 (total 7 residues) of instant SEQ ID NO:3 (see attachment 1, the right panel). The Homburger et al. peptide anticipates instant claims 24-26.

Conclusion

No claims are allowed.

Discussion of the art

The following art made of record and not currently relied upon in any rejections is considered pertinent to Applicants' disclosure:

• Drmanac et al. (WO 0175067, published 10/11/2001) teach polypeptide of SEQ ID NO:51020 which has 61.2% sequence identity to instant SEQ ID NO:3, wherein residues 1-546

(SEQ ID NO:51020) having 100% sequence identity to the sequence from residues 116-661 (SEQID NO:3). This reference is not prior art because Drmanac's polypeptide does not comprise the full-length SEQ ID NO:3 thereof as claimed in claim 18. Also, this reference is not prior art against claims 24-26 because the reference does not teach or suggest an oligopeptide having length ranging from 5 to 30 amino acid residues set forth in claims 24-26.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon, Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval IPAIRI system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAG only. For more information about the PAN system, see http://pairdirect.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Samuel W. Liu, Ph.D.

Patent Examiner, AU1653

September 21, 2006

VERAL INFORMATION:

Application US/07865166A

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; ORGANISM: Drosophila melanogaster
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ITLE OF INVENTION: Nucleic acids and proteins of Drosophila melanogaster
ILE REFERENCE: File Reference: 7326.094
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REGISTRATION NUMBER: 30,162
REFERENCE/DOCKET NUMBER: 0078
TELECOMMUNICATION INFORMATION:
TELEPHONE: (617) 542-5070
TELEPAX: (617) 542-8906
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COMPUTER: IBM PS/2 Model 50Z or 55SX
OPERATING SYSTEM: IBM P.C. DOS (Version 3.30)
SOFTWARE: WordPerfect (Version 5.0)
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APPLICANT: Homburger et al.

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TITLE OF INVENTION: Nucleic acids and proteins of Drosophila melanogaster FILE REFERENCE: File Reference: 7326-094

CURRENT APPLICATION NUMBER: US/09/270,767

CURRENT FILING DATE: 1999-03-17

NUMBER OF SEQ ID NOS: 62517

SOFTWARE: Patentin Ver. 2.0

SEQ ID NO 56389

TYPE: PRT

ORGANISM: Drosophila melanogaster

US-09-270-767-56389
                                                                                                                                                                                                                                                                                                                                                                     RESULT 12
US-09-270-767-56389
                                                                                                Query Match
                                                                                                                                                                                                                                                                                                                        GENERAL INFORMATION:
                                                                                                                                                                                                                                                                                                                                       Sequence 56389, Application US/09270767
Patent No. 6703491
                                                                                 Local
                            745 APPPPSE 751
                                                                                Similarity
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                                                             7; Conservative
APPPPSE 13
                                                                                               0.8%;
                                                       Score 7; DB 2; Pred. No. 26; 0; Mismatches
                                                                  DB
26,
                                                                                        2
                                                                                     Length 24;
                                                     0,
                                                  Gaps
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